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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

SMITHKLINE BEECHAM CORPORATION
d/b/a GLAXOSMITHKLINE,

Plaintiff,
v.

TEVA PHARMACEUTICALS USA, INC.,
Defendant.

**DOCUMENT ELECTRONICALLY
FILED**

Civil Action Nos. 02-3779 (JWB)
02-4537 (JWB)
(Chief Judge John W. Bissell)

**DEFENDANT'S OPPOSITION TO
PLAINTIFF'S MOTION IN LIMINE TO PRECLUDE TESTIMONY
BY DR. HARVEY KUPFERBERG BASED ON UNPRODUCED DATA**

DATE FOR ARGUMENT: November 22, 2004 at 10:00 a.m.

TABLE OF CONTENTS

	Page
INTRODUCTION.....	1
FACTS.....	1
ARGUMENT.....	2
CONCLUSION.....	5

TABLE OF AUTHORITIES

Cases	Page
<i>ABB Air Preheater, Inc. v. Regenerative Envtl. Co.</i> , 167 F.R.D. 668 (D.N.J. 1996).....	2
<i>Fitz, Inc. v. Ralph Wilson Plastics Co.</i> , 184 F.R.D. 532 (D.N.J. 1999).....	2, 3, 4, 5
<i>In re Paoli R. R. Yard PCB Litigation</i> , 35 F.3d 717 (3d Cir. 1994).....	2, 3, 4
<i>Myers v. Pennypack Woods Home Ownership Ass'n</i> , 559 F.2d 894 (3d Cir. 1977).....	2
<i>Reed v. Binder</i> , 165 F.R.D. 424 (D.N.J. 1996).....	5
Rules	
<i>Fed. R. Civ. P. 26</i>	4, 5

INTRODUCTION

Defendant Teva Pharmaceuticals USA, Inc. (“Teva”) submits this Opposition to plaintiff SmithKline Beecham’s (“SKB”) motion *in limine* by which SKB seeks to preclude any testimony by Dr. Harvey Kupferberg that is based on confidential information he acquired while employed by the National Institutes of Health (“NIH”). Dr. Kupferberg will abide by his obligations with the NIH and not disclose confidential data, and SKB has no basis for believing otherwise. However, Dr. Kupferberg’s general experience in reviewing these data is publicly available, not confidential, and to that extent, he is free to refer to it.

FACTS

In this patent infringement action, Teva has retained Dr. Harvey Kupferberg as an expert witness to testify with respect to facts and opinions that demonstrate that certain claims of the patent in suit are invalid for obviousness-type double patenting. Dr. Kupferberg has an extensive background in anticonvulsants. He has a Doctor of Pharmacy degree from the University of Southern California and a Ph.D. in Pharmacology from the University of California, San Francisco Medical Center. For this case, Dr. Kupferberg has prepared and submitted a comprehensive expert report, which describes, *inter alia*, his qualifications, compensation, prior work experience, publications, and opinions regarding the patent in suit, along with a list of all materials that he has considered in coming to his opinions.

From 1975 to 2000, Dr. Kupferberg was employed at NIH, where he was the project officer of the Anticonvulsant Screening Program (“ASP”). (*See* Exhibit 7A of the Final Pretrial Order (in Volume III)). During his deposition, SKB asked Dr. Kupferberg questions relating to whether his opinions were based on his “experience in reviewing ASP data of over 24,000 potential anticonvulsant compounds.” (*See, e.g.*, Kupferberg Dep., 78:1-87:1, 87:15-88:9, 89:19-

102:10; 104:20-105:11; 105:21-108:7; 295:7-300:18 (Exh. F)).¹ Dr. Kupferberg did not disagree with SKB that his general experience included his review of the ASP data. (Exh. F at 295:7-295:18). He also confirmed that a confidentiality agreement with the NIH existed, which precluded him from answering questions regarding specific compounds for which data was acquired as part of the ASP. (Exh. F at 78:1-78:12; 102:21-104:19; 295:7-295:11). Dr. Kupferberg, however, did confirm that he could discuss the data generally, if asked, and that the general experience he had acquired at the NIH in reviewing the ASP com[§]pounds is not confidential. (Exh. F at 296:17-300:18; 342:18-343:6; 358:6-15; *see, e.g.*, Krall reference (Exh. G); *see also, e.g.*, Porter reference (Exh. H)).

ARGUMENT

Exclusion is “an extreme sanction, not normally to be imposed absent a showing of willful deception or flagrant disregard of a court order by the proponent of the evidence.” *In re Paoli R. R. Yard PCB Litigation*, 35 F.3d 717, 791-92 (3d Cir. 1994) (overruling exclusion of expert testimony) (quoting *Myers v. Pennypack Woods Home Ownership Ass’n*, 559 F.2d 894, 905 (3d Cir. 1977) (same) (internal quotations omitted). “The Third Circuit has recognized that striking testimony is a severe sanction that should be used sparingly,” *Fitz, Inc. v. Ralph Wilson Plastics Co.*, 184 F.R.D. 532, 539 (D.N.J. 1999), and has “manifested a distinct aversion to the exclusion of important testimony absent evidence of extreme neglect or bad faith on the part of the proponent of the testimony.” *ABB Air Preheater, Inc. v. Regenerative Env’tl. Co., Inc.*, 167 F.R.D. 668, 671-672 (D.N.J. 1996) (citations omitted).

Far from meeting the *Paoli R. R. Yard* standard of “willful deception or flagrant disregard of a court order,” 35 F.3d at 792, Teva has neither deceived SKB nor disregarded any court order. Indeed, Teva is at a loss to determine what testimony SKB seeks to preclude. If it is the

¹ Exhibits F through I are attached to the Declaration of Robert J. Fettweis, Esq. In Support of Teva’s Defendant’s Oppositions to SKB’s Motions *In Limine* submitted contemporaneously herewith under seal.

specific data on the more than 24,000 compounds that Dr. Kupferberg could not disclose to SKB because of his confidentiality obligations, SKB need not have wasted the Court's time with its motion *in limine*. Dr. Kupferberg will abide by his agreement with the NIH.

Nevertheless, to the extent that Dr. Kupferberg's review of the ASP data has formed the basis of his general experience in the anticonvulsant field and informs the Court of his expertise, this general experience, as he has indicated, is not confidential and should not be precluded. Moreover, Dr. Kupferberg has never indicated that his expert opinions were based on any of the specific ASP data. Instead, they were based on the public summary information. (*See, e.g.*, Exh. F at 296:17-300:18; *see also* Exhibit 7 of the Final Pretrial Order (Volume III), at ¶ 76-77). The ASP data are relevant only to the extent that they show that Dr. Kupferberg's expertise is also drawn from his past experience in reviewing this data. Such general experiences are not confidential. (Exh. F at 296:17-300:18; 342:18-343:6). Indeed, some of this information is available from Dr. Kupferberg's publications, which were identified to SKB and upon which SKB could, and in some instances did, inquire at deposition. (*See, e.g.*, Exh. F at 127:6-128:14; 241:19-243:15; Krall reference (Exh. G); Porter reference (Exh. H)). Other such information was the subject of Dr. Kupferberg's deposition testimony. Therefore, any testimony from Dr. Kupferberg regarding opinions that would be based on general experience, which may include experience from his knowledge and public information relating to the ASP compounds, or which was covered by his expert report or at deposition, should not be precluded.

SKB has ignored the closest authorities on this issue. In *Paoli R.R. Yard*, 35 F.3d at 717, the Third Circuit overruled the district court's exclusion of expert testimony for failure to comply with the court's scheduling order. In that case, "Plaintiffs properly identified [the witness] by the ... deadline, thus the defendants knew that he was going to testify. They were also aware of the general substance of his testimony and even some of the specifics..." from the witness's deposition. *Id.* at 792. Accordingly, the Third Circuit found that "[t]he prejudice to the

defendants here is extremely minimal. . . Thus, in excluding [the proposed testimony], the district court abused its discretion.” *Id.* at 792-93.

Similarly, in *Fitz, Inc. v. Ralph Wilson Plastics Co.*, 184 F.R.D. 532 (D.N.J. 1999), the court refused to preclude an expert from testifying. Plaintiff employed an adhesive expert, who had been asked at his deposition questions relating to the basis of his opinions, acquired while employed at a former employer. The expert explained that a confidentiality agreement with his former employer precluded him from answering such questions with specific details regarding confidential information, such as adhesive formulations or developmental methodologies. The defendants moved to compel or preclude the expert from testifying. The court, however, determined that although the expert did not disclose the formulas or testing procedures of his former employer, he had provided substantial information concerning the basis of his opinion, such as scientific principles, literature and defendants’ own data, in addition to the knowledge that may have come for his years of experience and past tests performed at his former employer. The court held that the expert had provided a sufficient basis for his opinion. *Id.* at 539 (“one of the main purposes of Rule 26 is to prevent unfair surprise . . . there has been no unfair surprise to the defendants.”).

Here, Dr. Kupferberg has already provided to SKB a lengthy expert report that is more than sufficient to advise SKB as to how he arrived at his opinions. Indeed, SKB has had the opportunity to depose Dr. Kupferberg regarding his opinions and his general experience in the field. Moreover, as SKB knows, much of Dr. Kupferberg’s experience at the NIH is disclosed in publications of which Dr. Kupferberg was a co-author. They include a general overview of the testing and investigation of anticonvulsant compounds at the NIH pursuant to the Anticonvulsant Screening Program, as well as how that investigation progressed over time. (*See, e.g.*, Krall Reference (Exh. G); Porter Reference (Exh. H)). SKB was also able to examine Dr. Kupferberg regarding the “red book”, which related to the NIH’s data regarding lamotrigine. (*See* Exh. F at 87:15-89:18; “red book” (Exh. I, The Early Evaluation of Anticonvulsant Drugs)).

SKB relies on *Reed v. Binder*, 165 F.R.D. 424 (D.N.J. 1996). The facts there, however, are inapposite. In Reed, the court sanctioned defendants by having them bear the fees charged by their own expert witnesses for discovery depositions because their reports failed to comply with the standards of Rule 26(a). In contrast to Dr. Kupferberg, the proposed experts in that case failed to submit information regarding compensation, publication, prior testimony, documents relied on and a sufficient basis for their testimony. Not surprisingly, the court stated that these reports were “not sufficiently detailed, complete and in compliance with the Rule so that the plaintiffs would not be surprised.” *Id.* at 430. Even so, the court admitted the testimony of the experts in question.

As this Court noted in *Fitz, Inc.*, “[i]n cases where experts have been precluded for not providing an adequate basis for their opinion, they either provided no basis for their opinion ... or did not provide a complete statement of their opinions.” 184 F.R.D. at 538 (citations omitted). Here, Dr. Kupferberg has provided a complete statement of his opinions. Moreover, with regard to the specific ASP data at issue, Dr. Kupferberg will be abiding by his confidentiality agreement with the NIH. There is nothing to preclude.

CONCLUSION

For the foregoing reasons, to the extent that SKB seeks to preclude the testimony of Teva’s expert Dr. Kupferberg with its motion *in limine*, its motion should be denied.

Dated: November 8, 2004

Respectfully submitted,

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